ARTICLE

Outcomes of first 50 cases using a new pupil expander

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Purpose: To describe the initial experience with the Assia Pupil Expander 200 (APX-200, APX Ophthalmology) in eyes that underwent phacoemulsification or intraocular lens repositioning surgery that required mechanical pupil expansion.

Setting: Department of Ophthalmology, Meir Medical Center, Kfar-Saba, and Ein-Tal Eye Center, Tel Aviv, Israel.

Design: Retrospective case series.

Methods: The APX-200 is a single-use device, intended for mechanical expansion of the pupil during intraocular surgery. Two devices are inserted through 2 opposite 19-gauge incisions using designated forceps. The surgical course and early postoperative follow-up was recorded in 50 eyes.

Results: The study included 50 consecutive eyes, with mean preoperative pupil diameter was 3.7 mm. The APX effectively dilated the pupils in all cases. No complication related to the use of the APX such as hyphema, iridodialysis, or Descemet membrane detachment were noted in this series. A central and round pupil was restored in all eyes at 1-month postoperatively, with 14 eyes (28%) having mild sphincter tears. Pupilloplasty was not required in any of the cases.

Conclusions: The APX-200 was an effective and safe device for pupil expansion during intraocular surgery.

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Online Video

Intraocular surgery in eyes with small pupils is challenging and may significantly affect surgical outcomes. The small pupil size restricts the surgeon's field of view and increases the risk for iris trauma, capsular complications, zonular dehiscence, retained lens material, difficult intraocular lens (IOL) implantation, and vitreous loss.[1,2] Poorly dilating pupils are commonly seen in patients with pseudoexfoliation syndrome, uveitis, posttrauma, diabetes mellitus, advanced age, and prolonged use of miotic eyedrops for glaucoma. Intraoperative floppy-iris syndrome (IFIS), described in 2005, is associated with pupil constriction during surgery, secondary to atrophy of the iris dilator muscle and decreased iris tissue rigidity.[3–6] Complication rates in patients with IFIS have been reported to be up to 12.5%.[4]

Pupillary dilation can be achieved intraoperatively with pharmacological or mechanical techniques that include iris hooks and pupillary rings (closed or open). Typically, these insertion and removal of these devices require intraocular manipulation.

The Assia Pupil Expander (APX, APX Ophthalmology) is a spring-loaded device consisting of 2 limbs with a pivot pin centrally to form a scissor-like device. The first generation (APX-100) was a reusable metallic device introduced in 2013. The second-generation device, APX-200, was developed in 2015 and is disposable. It is approved for clinical use in the United States (510[k] exempt) and is European Conformity marked. This device was developed as an alternative option for pupil expansion that is quick and simple to insert and remove, requiring minimal intraocular manipulation, and provides adequate pupil size without interfering with subsequent surgical steps. This study reports our initial clinical experience with the APX-200 in 50 consecutive eyes that fit the inclusion criteria.

METHODS

This study was conducted in the Ophthalmology Department of Meir Medical Center, a tertiary referral center in Israel. Fifty eyes from 41 patients were included.

Patients with a minimum pupil diameter of 2.0 mm and a maximum pupil diameter of 4.5 mm or lesser after pharmacological dilation with tropicamide 0.5% (Mydramide) and phenylephrine HCl 10% (Efrin 10) were included in the study. Exclusion criteria were aged younger than 18, only 1 functional eye (visual acuity less than 20/200 in the other eye),

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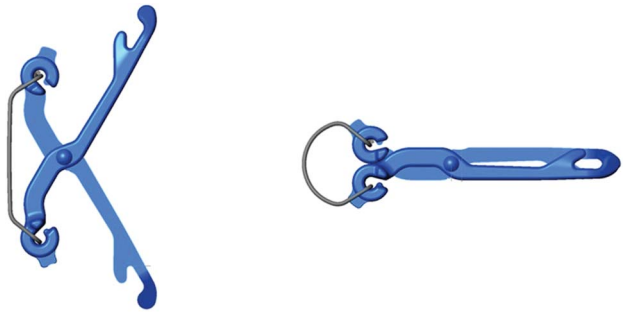

Figure 1. The design of the APX-200. APX = Assia Pupil Expander

active uveitis, or severe iris damage. Most eyes selected had surgical risk factors such as pseudoexfoliation syndrome, posterior synechiae, previous use of systemic α-receptor blockers or pilocarpine, narrow angle glaucoma, hypermature, and Morgagnian cataracts. Forty-seven eyes underwent phacoemulsification. Two nanophthalmic eyes of the same patient (operated separately) were included in the study. An eye with a severely phacodonetic cataract secondary to pseudoexfoliation was treated with cataract extraction, posterior chamber IOL (PC IOL) implantation, and capsular bag fixation using the capsular anchor (AssiAnchor, Hanita Lenses) Three cases were treated for subluxated PC IOL with IOL repositioning and scleral suture fixation. The study was approved by the local Institutional Review Board.

Patients underwent complete preoperative biomicroscopic evaluation and were followed up postoperatively for at least 1 month. Intraoperative and postoperative complications were recorded.

Surgical Technique

The APX-200 is a single-use device. It is supplied as a kit containing 2 devices and 2 specially designed forceps. It incorporates 2 Nylon arms with hooks on their distal ends for stable pupil margin engagement and a Nitinol spring designed to expand the iris gently. The hooks are slightly bent to optimize iris capture. The device creates a wide, quadrangular pupillary aperture of approximately 6.0 mm. The open and closed states of the device can be seen in Figure 1. The APX-200 is designed to provide expansion of the pupillary aperture in cases of a poorly dilating pupil or IFIS, enabling adequate visualization of the surgical field to facilitate intraocular surgery. To remove the device from its repository, specially designed forceps are inserted through an opening to grasp the trailing ends of the APX, adjacent to the spring. Pinching of the forceps will close the limbs of the device, facilitating withdrawal from the repository. These steps can be performed by the scrub nurse. The forceps can be locked in the closed position by a sliding mechanism on the forceps to enable easy transfer between the scrub nurse and the surgeon.

All operations were performed by a single surgeon (E.I.A.). After administration of topical and intracameral anesthesia, a paracentesis was made parallel to iris plane at the corneal limbus, using a 19-gauge (1.1 mm) microvitreoretinal lance. The anterior chamber was then filled with a cohesive ophthalmic viscosurgical device (OVD). A small amount of OVD was injected between the iris and the anterior capsule to create space for the leading ends of the APX-200 to engage the pupil margin. A second paracentesis incision was made on the opposite corneal limbus to insert a second APX. The expander was then inserted through the paracentesis until the pivot pin was located within the corneal tunnel (Figure 2, A). The grip on the forceps was slowly released to deploy the leading ends of the APX to engage and stretch the pupil before full release on confirmation of proper engagement of the pupil margin (Figure 2, B). Avoidance of the downward pressure of the anterior lens capsule is recommended. The same procedure was repeated through the second paracentesis to deploy the second APX (Figure 2, C). Placement of the APX can be varied according to surgical needs. The 2 APX devices can be placed directly opposite each other to create a wide, quadrangular pupillary aperture of approximately 6.0 mm. A slight skewing of the incisions creates a trapezoidal opening with the wide base facing the surgeon. This provides a large, device-free area for other surgical instruments without interference from the limbs of the APX (Figure 2, D). The APX was removed at the end of surgery using the same forceps with the steps performed in reverse (Figure 2, E). The pupil usually returns to its natural, preoperative shape (Figure 2, F). The OVD was removed at the end of the surgery, and intracameral antibiotics injected, with corneal incisions closed by wound hydration (Video 1, http://links.lww.com/JRS/A340). Postoperatively, all patients were treated with ofloxacin eyedrops, 5 times daily during the first week and prednisolone acetate 1% eyedrops, 5 times daily for 1 month with tapering down after 1 week. A slight variation of the insertion technique is recommended for surgeons who are not familiar with the APX. The APX can be allowed to fully

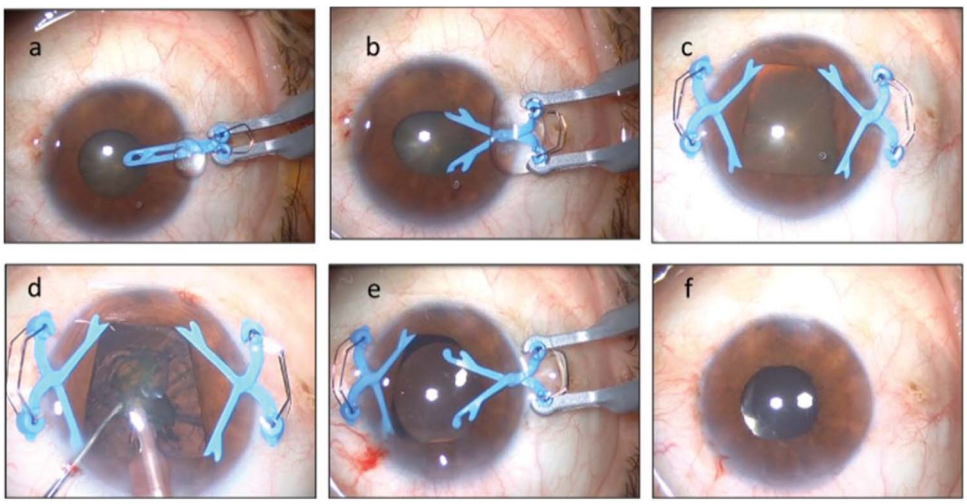

Figure 2. The APX-200 in clinical use: (*A*) The APX-200 was inserted through a 19-gauge paracentesis using designated forceps. *B:* The curved blunt tips of the APX-200 were positioned behind the iris, and the device was slowly released. *C:* A trapezoidal shaped pupillary opening was created when the stab incisions were placed off-axis from each other. The wider base was facing the surgeon and provided a large device-free area. *D:* Phacoemulsification was performed comfortably under direct visualization. The APX-200 did not interfere with surgical maneuvers. *E:* After IOL implantation, a reverse process was used to remove the APX with the supplied forceps. *F:* At the end of the surgery, the pupil returned to the preoperative size and shape. APX = Assia Pupil Expander

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Table 1. Preoperative Factors Associated With Poor Pupil Dilation and Difficult Surgery.

Preoperative evaluation	Frequency (n)	Percentage
Posterior synechiae	11	22
Shallow anterior chamber	6	12
Pseudoexfoliation	22	44
Previous uveitis	4	8
Preexisting glaucoma	15	30
Pilocarpine use	4	8
α-Blocker use	18	36
Type 2 diabetes	16	32

open in the anterior chamber prior to any engagement of the pupil margins. The device is then pinched slightly with the forceps to engage each limb to the pupil margin in turn. Breaking down the APX deployment into more distinct steps may prevent instances of anterior segment trauma for inexperienced surgeons who may lose grip and control of the device during its insertion.

RESULTS

The mean preoperative postdilation pupil diameter was 3.7 mm in this series. The most common etiology of inadequate pupillary dilation was pseudoexfoliation syndrome, which was seen in 22 eyes (44%). A poorly dilating pupil was associated with α-blocker use in 18 eyes (36%), prior uveitis (4 eyes [8%]) and pilocarpine usage (4 eyes [8%]). Posterior synechiae was present in 11 eyes (22%), and synechiolysis was performed on all these eyes prior to APX use (Table 1).

In all 50 cases, the surgeries were performed successfully with effective pupil dilation throughout the surgery. No or minor intraoperative bleeding from the iris was noted in all of our cases. There were no other APX-related complications such as hyphema, iridodialysis, or Descemet membrane detachment.

Of the 50 eyes, phacoemulsification using the phacoemulsification-chop technique was performed in 47 cases. Forty-six cases had in-the-bag implantation of a foldable posterior IOL (AcrySof, Alcon Laboratories, Inc., or SeeLens AF, Hanita Lenses). In a case with hypermature cataract and posterior synechia, the fibrotic anterior capsule was cut with scissors, and a 3-piece AcrySof IOL was implanted (Figure 3, A–D).

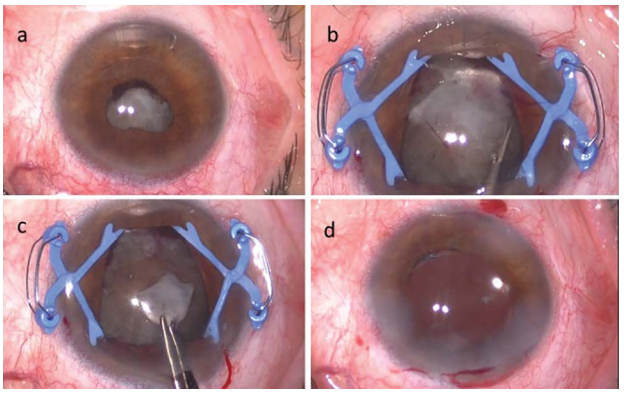

Figure 3. APX-200 was used in a patient with long-standing anterior uveitis and hypermature cataract. *A:* Posterior synechia and fibrotic anterior capsule were seen through the constricted pupil. *B:* The dense anterior capsule was cut using scissors under direct visualization. *C:* The anterior capsule was removed, and the advanced nuclear cataract was exposed. *D:* The 3-piece IOL was stable and central. APX = Assia Pupil Expander

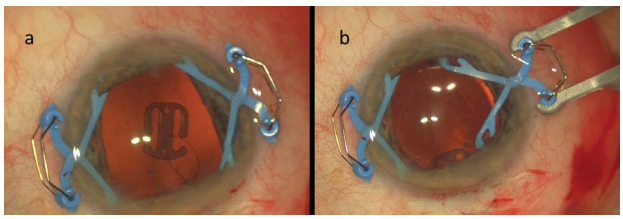

Figure 4. Iridophacodonesis in a patient with advanced pseudoexfoliation. *A:* After careful lens removal, a capsular anchor was inserted to secure the lens capsular bag to the superior scleral wall. *B:* The APX was removed after IOL implantation within the stabilized capsular bag. The knot of the 9-0 polypropylene suture was buried into the scleral tissue. APX = Assia Pupil Expander

Preoperative phacodonesis was seen in 4 eyes. In 1 case, the patient had relatively mild Marfan syndrome, and the PC IOL was implanted into the capsular bag with a capsular tension ring. Phacodonesis in the other 3 cases was secondary to zonular weakness from pseudoexfoliation syndrome. The first case had uneventful in-the-bag implantation of PC IOL. In the second patient, a single capsular anchor (Hanita Lenses Ltd.) was used as a capsule-stabilizing device to secure the lens IOL–capsular bag complex to the scleral wall (Figure 4, A and B). The third case required anterior vitrectomy and implantation of an anterior chamber IOL. Three patients underwent repositioning and scleral fixation of the existing PC IOL using 9-0 Prolene sutures (MANI) and anterior vitrectomy (Figure 5, A and B). Adequate pupil expansion was also achieved with the APX-200 in 3 cases that underwent IOL repositioning and scleral fixation. Good visualization was especially crucial in such surgery as it involves precise positioning of the sutures and additional intraocular manipulations.

Postoperatively, a round pupil was maintained in all eyes at 1 month postoperatively, with 14 eyes (28%) having mild sphincter tears such as focal irregularities of the pupil margin seen postoperatively or intraoperatively associated with self-limiting hemorrhage from these areas. No pupil became severely irregular or atonic that required surgical intervention to constrict the pupil. Corneal edema was seen in 4 eyes (8%) at the postoperative day 1, all of which resolved spontaneously by the postoperative week 1 follow-up. High intraocular pressure was noted in 3 eyes

Table 2. Postoperative Findings.

Finding	Frequency (n)	Percentage
Corneal edema	4	8
IOP elevation	3	6
Sphincter irregularity	14	28

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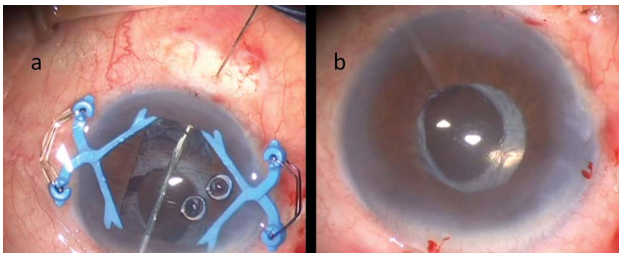

Figure 5. Scleral fixation of subluxated PC IOL in the bag. *A:* The long needle of the 9-0 polypropylene suture was introduced posterior to the IOL haptic, penetrated the lens capsule, and externalized using a 27-gauge needle inserted through a paracentesis in the opposite direction. The needle was then reinserted, directed anterior to the same haptic and externalized adjacent to the initial suture penetration. *B:* After the APX-200 was removed, the pupil regained its round contour, and the IOL was stable and well centered. APX = Assia Pupil Expander; PC IOL = posterior chamber IOL

(maximum of 32 mm Hg) and was managed by topical administration of intraocular pressure-lowering medication in the early postoperative period. None of the operated eyes experienced cystoid macular edema or persistent inflammation. These findings are summarized in Table 2.

DISCUSSION

Intraoperative small pupil is a challenge even to experienced ophthalmic surgeons. Pupil enlargement techniques usually include pharmacological dilation, viscomydriasis, and mechanical stretching of the pupil.

A combination of topical and intracameral mydriatic administration can provide sufficient pupil expansion in a proportion of patients with poorly dilating pupils using combination of lidocaine and epinephrine intracamerally.[7] OVDs injected into the anterior chamber provide some degree of pupil expansion, but repeated intraoperative injections may be required to maintain adequate dilation throughout the surgery.

Surgical maneuvers for pupil expansion include pupil stretching, sphincterotomies, and synechiolysis.[2,8] Pupil stretching and synechiolysis may not occasionally provide sufficient mydriasis; however, care must be taken to avoid overstretching as this may result in iris bleeding, pigment dispersion, postoperative pupil atony, and cystoid macular edema.[9–11] The use of sphincterotomies for pupil enlargement has generally been abandoned by most surgeons despite some reports with good clinical results.[12,13]

Two types of pupillary dilators commercially available are hooks and rings. The use of iris hooks for pupil expansion has gained worldwide popularity since their introduction in the early 1990s.[14,15] Iris hooks help achieve an enlarged, stable pupillary aperture of any desired size. They are useful in keeping the pupil margin away from the phacoemulsification tip in cases of IFIS and can serve to support the lens capsule when positioned at the capsulorhexis edge in cases of zonular weakness. Iris hooks require additional paracenteses (4 to 5) for insertion and can increase the surgical time.

Pupillary rings provide circumferential expansion of small pupils in a more physiological plane compared with iris hooks, cause less trauma to the iris sphincter and prevent iris billowing during surgery. A major advantage of all rings is that they are inserted through the main surgical incision and do not require additional incisions. Numerous designs of ring expanders are available in the market including open and closed rings made of poly(methyl methacrylate) (PMMA), silicon, polypropylene, polyurethane, and metal. The Malyugin ring (MicroSurgical Technology) is the most popular device. It is available in 2 sizes—6.25 mm and 7.0 mm, and is implanted and removed using a specially designed injector.[8,16,17]

The APX-200 was developed as an alternative means of effective pupil expansion during intraocular surgery. Its insertion is simple and intuitive, and it enlarges the pupil to approximately 6.0 mm. In cases with IFIS, the iris was held relatively taut by the APX, which prevented prolapse through the incisions. The advantage of the APX compared with ring expanders lies in its deployment technique, as it directly engages the pupil margin by control from outside the eye and no intraocular manipulations for placement is required. Since the device is never completely intraocular, there is no risk for it falling into the vitreous cavity in cases of posterior capsule rupture.

Akman et al. compared 4 types of pupil dilating devices: iris-retractor hooks (Synergetics, Inc.), the Beehler pupil dilator (Moria), bimanual pupil stretching with push-and-pull collar-button iris retractors, and a PMMA pupil-dilator ring (Morcher). Iris sphincter ruptures were noted in 4 (40%) of the 10 eyes using iris-retractor hooks, 4 (40%) of the 10 eyes using the Beehler dilator, 3 (30%) of the10 eyes with bimanual stretching, and 1 (10%) of the 10 eyes using the PMMA pupil-dilator ring. All pupils regained their preoperative shape in 2 weeks.[1] Tian et al. compared postoperative iris distortion with the diamond-shaped Malyugin ring and the circular Visitec I-Ring iris dilators and found that the circular ring resulted in 11% iris distortion when compared with 49% with the Malyugin ring[17] The APX is relatively gentle to the iris sphincter with 14 eyes (28%) having focal pupil margin irregularities. .No other device-related adverse event was recorded in this study. The APX was effective for routine cataract surgery in eyes with nondilating pupils and in eyes with more complex features such as IFIS, mature and hypermature cataracts, shallow anterior chambers, irregular and decentered pupils, severe phacodonesis, and malpositioned IOLs.

In conclusion, the APX-200 is a new pupil expander with specific features in its design and clinical use. The ease of insertion and removal with the disposable delivery system makes it a desirable alternative when treating small pupils. The APX can be used in standard phacoemulsification cataract extraction surgery and complicated intraocular surgery.

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WHAT WAS KNOWN

- Small pupils can be dilated during intraocular surgery using pharmacological or mechanical methods.
- Available pupil expanders include iris hooks and pupillary rings.

WHAT THIS PAPER ADDS

- The APX-200 device is an effective alternative device for expanding small pupils.
- It is relatively simple to use, required no or minimal intraocular manipulations, and maintained good postoperative pupil shape and contour.

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